



BILLING CODE 6560-50-P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2012-0509; FRL-9903-53]

#### Isopyrazam; Pesticide Tolerances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of isopyrazam in or on apple and peanut for which there are no accompanying United States registrations.

Syngenta Crop Protection, Inc., requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

#### SUPPLEMENTARY INFORMATION).

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2012-0509, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor

instructions and additional information about the docket available at

<http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Lois Rossi, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7090; email address: [RDfRNotices@epa.gov](mailto:RDfRNotices@epa.gov).

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

*B. How Can I Get Electronic Access to Other Related Information?*

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at [http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl). To access the OCSPP test guidelines referenced in this document electronically, please go to <http://www.epa.gov/ocspp> and select "Test Methods and Guidelines."

*C. How Can I File an Objection or Hearing Request?*

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2012-0509 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the **Federal Register***]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2012-0509, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

## **II. Summary of Petitioned-For Tolerance**

In the **Federal Register** of September 28, 2012 (77 FR 59578) (FRL-9364-6), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 2E8039) by Syngenta Crop Protection, Inc., 410 Swing Rd., P.O. Box 18300, Greensboro, NC 27419-8300. The petition requested that 40 CFR 180.654 be amended by establishing tolerances for residues of the fungicide isopyrazam, in or on apple at 0.6 parts per million (ppm) and peanut at 0.01 ppm. That document referenced a summary of the petition prepared by Syngenta Crop Protection, Inc., the registrant, which is available in the docket, <http://www.regulations.gov>. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition EPA has proposed a higher tolerance level for apple. The reason for this change is explained in Unit IV.D.

There are no registered food uses for isopyrazam in the United States. These tolerances were requested in connection with use of isopyrazam on apples and peanuts grown outside the United States. These tolerances will allow apples and peanuts containing isopyrazam residues to be imported into the United States.

### **III. Aggregate Risk Assessment and Determination of Safety**

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for isopyrazam including exposure resulting from the tolerances established by this action. EPA’s assessment of exposures and risks associated with isopyrazam follows.

#### *A. Toxicological Profile*

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Subchronic and chronic oral toxicity studies in the rat, mouse, and dog demonstrate that the primary target organ for isopyrazam is the liver (increased organ weight and centrilobular hepatocyte hypertrophy). Liver toxicity is usually accompanied by reductions in bodyweight and food consumption.

Isopyrazam did not cause reproductive toxicity. Effects seen in the offspring (bodyweight gain during lactation and increase liver weight at weaning) in the rat reproduction study occurred at the same doses that cause general toxicity in the parents. Developmental effects described as small eyes and/or microphthalmia were observed in both the Himalayan and New Zealand rabbit strains. However, in the Himalayan strain, the intraocular abnormalities occur in the absence of maternal toxicity while in the New Zealand the ocular abnormalities occurred at doses that were maternally toxic. Developmental effects observed in the rat (increased post-implantation loss, reduced fetal weight and a slight retardation of ossification) occurred at doses that also produced maternal toxicity (mortality, decreased body weights, body weight gains, and food consumption).

No evidence of specific neurotoxicity was seen in acute and subchronic oral neurotoxicity studies in rats. Clinical signs seen in two subchronic dog studies (side-to-side head wobble, ataxia, reduced stability) are consistent with neurotoxic effects. However detailed and specific neuropathological analyses were not conducted for the dog studies (i.e., functional observational battery, motor activity, detailed histopathology with special stains). Consequently, there is uncertainty regarding whether the effects seen in the dog studies are in fact signs of neurotoxicity. However, clear no observed adverse effect levels (NOAELs)/lowest adverse effect levels (LOAELs) were established for both subchronic dog studies. The point of departure selected for the acute dietary assessment

is based on clinical signs seen on day 2 in one of four males in the subchronic dog study. This study provides the lowest NOAEL in the database (most sensitive endpoint) for a single dose effect. The dose used for the chronic dietary risk assessment is eight times lower than the dose at which clinical effects were seen at four weeks in the second subchronic dog study.

There is no evidence of immunotoxicity based on a 28-day dietary immunotoxicity study in rats. The LOAEL for immunotoxicity was not identified and the NOAEL for immunotoxicity was 1,356 milligrams/kilograms (mg/kg).

Isopyrazam is classified as “Likely to be Carcinogenic to Humans” based on increased incidence of uterine endometrial adenocarcinomas and liver hepatocellular adenomas in female rats and increased incidence of thyroid follicular cell adenomas and/or carcinomas in male rats. Isopyrazam is not carcinogenic in the mouse. There is no evidence of genotoxicity, mutagenicity, or clastogenicity in the *in vivo* and *in vitro* studies. There are no structural relationships with other known carcinogens. A linear low-dose approach ( $Q_1^*$ ) was used to extrapolate experimental animal tumor data for the quantification of human cancer risk.

Isopyrazam is of low acute toxicity by the oral, dermal, and inhalation routes and is not a skin or eye irritant.

Specific information on the studies received and the nature of the adverse effects caused by isopyrazam as well as the NOAEL and the LOAEL from the toxicity studies can be found at <http://www.regulations.gov> in the document “Human Health Risk Assessment for the Establishment of Tolerances with No U.S. Registrations for Isopyrazam in/on Imported Apple and Peanut” at pp. 14-18 in docket ID number EPA-HQ-OPP-2012-0509.

### *B. Toxicological Points of Departure/Levels of Concern*

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level -- generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) -- and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>. A summary of the toxicological endpoints for used for human risk assessment is shown in Table 1 of this unit.



**TABLE 1.--SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR ISOPYRAZAM FOR USE IN HUMAN HEALTH RISK ASSESSMENT**

<b>Exposure/ Scenario</b>	<b>Point of Departure (mg/kg/day)</b>	<b>Uncertainty/ FQPA Safety Factors</b>	<b>RfD, PAD, Level of Concern for Risk Assessment (mg/kg/day)</b>	<b>Study and Toxicological Effects</b>
Acute Dietary (All populations)	NOAEL= 30	UF <sub>A</sub> = 10x UF <sub>H</sub> =10x FQPA SF= 1x	Acute RfD = 0.30 aPAD = 0.30	Subchronic Toxicity-- Dog LOAEL = 100 mg/kg/day based on clinical signs (side-to-side head wobble) in male dogs.
Chronic Dietary (All populations)	NOAEL= 5.5	UF <sub>A</sub> = 10x UF <sub>H</sub> =10x FQPA SF= 1x	Chronic RfD = 0.055 cPAD = 0.055	Chronic Toxicity/Carcinogenicity- -Rats LOAEL = 27.6 mg/kg/day based on decreased body weight and body weight gain in females; increased incidences of hepatocellular hypertrophy, pigment in centrilobular hepatocytes, eosinophilic foci of altered hepatocytes, vacuolation of centrilobular hepatocytes, bile duct hyperplasia, and bile duct fibrosis in both sexes; and brown pigment in the kidney in females.
Cancer (All routes)	Classification: CARC classified isopyrazam as “Likely to be Carcinogenic to Humans” based on increased liver and uterine endometrial epithelial tumors in female rats and increased thyroid follicular cell tumors in male rats. A cancer slope factor (Q <sub>1</sub> *) of 0.00629 (mg/kg/day) <sup>-1</sup> was calculated based on an increase in increase in liver tumors in female rats.			

CARC = Cancer Assessment Review Committee. Food Quality Protection Act Safety Factor = FQPA SF. LOAEL = lowest observed adverse effect level. mg/kg/day = milligram/kilogram/day. NOAEL = no observed adverse effect level. PAD = population adjusted dose (a = acute, c = chronic). Point of Departure = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. Q<sub>1</sub>\* = Linear low-dose approach. RfD = reference dose. UF = uncertainty factor. UF<sub>A</sub> = extrapolation from animal to human (interspecies). UF<sub>H</sub> = potential variation in sensitivity among members of the human population (intraspecies).

### *C. Exposure Assessment*

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to isopyrazam, EPA considered exposure under the petitioned-for tolerances as well as all existing isopyrazam tolerances in 40 CFR 180.654. EPA assessed dietary exposures from isopyrazam in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. In estimating acute dietary exposure, EPA used food consumption information from the U.S. Department of Agriculture (USDA) 2003-2008 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, maximum residues of isopyrazam (as the sum of its *syn*-isomer and *anti*-isomer) plus its tertiary alcohol metabolite (CSCD460260; as the sum of its *syn*-isomer (CSCD459488; free and conjugated) and *anti*-isomer (CSCD459489; free and conjugated)) from field trials reflecting maximum use rates and 100 percent crop treated (PCT) assumptions were used. Dietary Exposure Evaluation Model (DEEM) default processing factors were used for all processed commodities including dried apple (8.0), apple juice/cider (1.3), dried banana/plantain (3.9), and peanut butter (1.89). In the absence of peanut processing data, the maximum theoretical concentration factor was used for peanut oil (2.8).

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment, EPA used the food consumption data from the USDA 2003-2008 NHANES/WWEIA. As to residue levels in food, EPA used the same residue levels, processing factors and PCT assumptions as in the acute dietary exposure analysis.

iii. *Cancer.* Isopyrazam is classified as “Likely to be Carcinogenic to Humans” based on increased liver and uterine endometrial epithelial tumors in female rats and increased thyroid follicular cell tumors in male rats. In the absence of mode of action data, a linear low dose extrapolation for cancer risk assessment was used. A cancer slope factor ( $Q_1^*$ ) of  $0.00629 \text{ (mg/kg/day)}^{-1}$  was used for the quantification of human cancer risk. In evaluating cancer risk, EPA used the same residue levels, processing factors, and PCT assumptions as the acute and chronic dietary exposure analyses.

iv. *Anticipated residue and PCT information.* While EPA did not use PCT information in the dietary assessment for isopyrazam, anticipated residues were used. Maximum residues from field trials conducted at the maximum use rates were used to estimate residues of isopyrazam (as the sum of its *syn*-isomer and *anti*-isomer) plus its tertiary alcohol metabolite (CSCD460260; as the sum of its *syn*-isomer (CSCD459488; free and conjugated) and *anti*-isomer (CSCD459489; free and conjugated)). Analyses assumed 100 PCT and used DEEM default processing factors. In the absence of peanut processing data, the maximum theoretical concentration factor was used as a processing factor for peanut oil (2.8).

Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E)

and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

2. *Dietary exposure from drinking water.* An assessment of residues in drinking water is not needed for isopyrazam because there is no drinking water exposure associated with the existing (banana) and proposed uses (apple and peanut) which are all non-domestic.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Isopyrazam is not registered for any specific use patterns that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

EPA has not found isopyrazam to share a common mechanism of toxicity with any other substances, and isopyrazam does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that isopyrazam does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

#### *D. Safety Factor for Infants and Children*

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional SF when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There are no residual uncertainties for pre- and/or post natal susceptibility even though qualitative susceptibility was observed in the range-finding developmental studies in rabbits. Developmental effects (eye abnormalities) were observed in the absence of maternal toxicity in two range finding developmental toxicity studies in the Himalayan rabbit. However, the eye effects were only observed at relatively high doses (200-400 mg/kg/day) with clear NOAELs/LOAELs established for the developmental effects. Developmental effects observed in the rat (reduced fetal weight and a slight retardation of ossification) occurred only at doses that also produced maternal toxicity (mortality, decreased body weights, body weight gains, and food consumption). There was no evidence of increased susceptibility in a 2-generation reproduction study following pre- or postnatal exposure to isopyrazam. There was also no evidence of neuropathology or abnormalities in the development of the fetal nervous system from the available toxicity studies conducted with isopyrazam. Clear NOAELs/LOAELs were established for the developmental effects observed in rats and rabbits as well as for the offspring effects (increased liver

weights) seen in the 2-generation reproduction study and a dose-response relationship for the effects of concern is well characterized. The dose used for the acute dietary risk assessment (30 mg/kg/day), based on effects seen in the subchronic dog study, is protective of the developmental effects seen in rats (44.5 mg/kg/day) and rabbits (200 mg/kg/day). Based on these considerations, there are no residual uncertainties for pre- and/or postnatal susceptibility

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

- i. The toxicity database for isopyrazam is complete.
- ii. As discussed in Unit III.D.2, there are no residual uncertainties for pre-and/or postnatal susceptibility and thus, it is unnecessary to retain the 10X FQPA SF to adequately protect infants and children.
- iii. The dietary risk assessment is based on parent plus metabolite residues and will not underestimate dietary exposure to isopyrazam. For the acute, chronic and cancer dietary analyses, maximum residues of parent plus metabolite and 100 PCT assumptions were used for all treated commodities. There are no residual uncertainties identified in the exposure databases.

#### *E. Aggregate Risks and Determination of Safety*

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term

risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to isopyrazam will occupy 4.2% of the aPAD for children 1-2 years old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to isopyrazam from food will utilize 6.1% of the cPAD for children 1-2 years old, the population group receiving the greatest exposure.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account short- and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Isopyrazam is not registered in the United States. Short- and intermediate-term risk is assessed based on short- and intermediate-term residential exposure plus chronic dietary exposure. Because there is no short- or intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD, no further assessment of short- or intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short- and intermediate-term risk for isopyrazam.

4. *Aggregate cancer risk for U.S. population.* Using the exposure assumptions discussed in this unit for cancer exposure, the cancer dietary risk estimate for the U.S. population is  $2 \times 10^{-6}$ .

EPA generally considers cancer risks (expressed as the probability of an increased cancer case) in the range of 1 in 1 million (or  $1 \times 10^{-6}$ ) or less to be negligible. The

precision that can be assumed for cancer risk estimates is best described by rounding to the nearest integral order of magnitude on the logarithmic scale; for example, risks falling between  $3 \times 10^{-7}$  and  $3 \times 10^{-6}$  are expressed as risks in the range of  $10^{-6}$ . Considering the precision with which cancer hazard can be estimated, the conservativeness of low-dose linear extrapolation, and the rounding procedure described above, cancer risk should generally not be assumed to exceed the benchmark level of concern of the range of  $10^{-6}$  until the calculated risk exceeds approximately  $3 \times 10^{-6}$ . This is particularly the case where some conservatism is maintained in the exposure assessment. For isopyrazam, EPA's exposure assessment assumes maximum residues of concern from field trials reflecting the maximum use rates, default processing factors, the maximum theoretical concentration for residues in peanut oil and 100 PCT, which is highly conservative. Accordingly, EPA has concluded the cancer risk from exposure to isopyrazam falls within the range of  $1 \times 10^{-6}$  and is thus negligible.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population or to infants and children from aggregate exposure to isopyrazam residues.

#### **IV. Other Considerations**

##### *A. Analytical Enforcement Methodology.*

Adequate enforcement methodology (Method GRM006.01B) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; e-mail address: [residuemethods@epa.gov](mailto:residuemethods@epa.gov).



### *B. International Residue Limits*

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs). MRLs established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

No Codex or MRLs have been established for residues of isopyrazam in or on apple or peanut commodities.

### *C. Response to Comments*

EPA received a comment to the notice of filing which said that no residues of isopyrazam should be permitted on food. The Agency understands the commenter's concerns and recognizes that some individuals believe that pesticides should be banned on agricultural crops. However, the existing legal framework provided by FFDCA section 408 states that tolerances may be set when persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. This citizen's comment appears to be directed at the underlying statute and not EPA's implementation of it; the citizen has made no contention that EPA has acted in violation of the statutory framework.

#### *D. Revisions to Petitioned-For Tolerances*

For the purposes of harmonization with a pending European Union MRL for residues of isopyrazam in or on pome fruit (0.7 mg/kg), EPA is establishing a tolerance of 0.70 ppm in or on apple in lieu of the 0.6 ppm as requested by the petitioner. This increase to the proposed tolerance is supported by the data reviewed for the petition. No changes were made to the proposed tolerance for peanut.

#### **V. Conclusion**

Therefore, tolerances are established for residues of isopyrazam in or on apple at 0.70 ppm and peanut at 0.01 ppm. The Agency is also revising the tolerance expression to clarify that determining compliance with the tolerance requires measuring both the *syn*-isomer and the *anti*-isomers of isopyrazam. This change is supported by the available enforcement method which sums the two isomers for the tolerance detection. The tolerance expression revision will not impact the current banana tolerance.

#### **VI. Statutory and Executive Order Reviews**

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction

Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

## VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: December 19, 2013.

Lois Rossi,

*Director, Registration Division, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

**PART 180--[AMENDED]**

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

2. In § 180.654:

a. Revise the introductory text in paragraph (a).

b. Add alphabetically the commodities “Apple” and “Peanut” to the table in paragraph (a).

c. Revise footnote one to the table in paragraph (a).

The additions and revisions read as follows:

**§ 180.654 Isopyrazam; tolerances for residues.**

(a) *General.* Tolerances are established for residues of the fungicide isopyrazam, including its metabolites and degradates, in or on the commodities listed in the following table. Compliance with the tolerance levels specified in the following table is to be determined by measuring only isopyrazam (3-(difluoromethyl)-1-methyl-*N*-[1,2,3,4-tetrahydro-9-(1-methylethyl)-1,4-methano-naphthalen-5-yl]-1*H*-pyrazole-4-carboxamide), as the sum of its *syn*-isomer (3-(difluoromethyl)-1-methyl-*N*-[(1*RS*, 4*SR*, 9*RS*)-1,2,3,4-tetrahydro-9-(1-methylethyl)-1,4-methanonaphthalen-5-yl]-1*H*-pyrazole-4-carboxamide) and *anti*-isomer (3-(difluoromethyl)-1-methyl-*N*-[(1*RS*, 4*SR*, 9*SR*)-1,2,3,4-tetrahydro-9-(1-methylethyl)-1,4-methano-naphthalen-5-yl]-1*H*-pyrazole-4-carboxamide) in or on the commodity.

Commodity	Parts per million
Apple <sup>1</sup>	0.70
* * *	* *
Peanut <sup>1</sup>	0.01

<sup>1</sup>There are no U.S. registrations for use of isopyrazam on apple, banana, or peanut.  
\* \* \* \* \*

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